LUITPOLD

March 16, 1999

0551 '99 MAR 19 P2:08

VIA CERTIFIED MAIL

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Comments to Docket Number 98D-1266

Dear Sir or Madam:

Luitpold Pharmaceuticals, Inc. appreciates the offered comment period regarding the *Draft Guidance for Industry on Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling.* As stated in the Federal Register dated January 28, 1999, the inclusion of a therapeutic equivalence code on prescription drug labels/labeling is voluntary, however, Luitpold submits the following comments.

1. The therapeutic equivalence rating letter code is published in the *Orange Book* which is readily available, including on the FDA's website.

2. Placement of the code on the immediate container labeling is not prudent due to lack of space, especially on small volume injectable products (0.5 mL to 10.0 mL). FDA Modernization Act of 1997 eliminated the legend statement "Federal Law prohibits dispensing without prescription" to reduce unnecessary label clutter. Placement of code and statement could be placed in the package insert.

3. The therapeutic equivalence statement will detract from the primary purpose of a drug label - to assist the use in proper identification of the product contents. If the label is difficult to read, it therefore increases the risk of medication errors due to product misidentification. 21 CFR 201.15(a)(4) states "A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 502(c) of the act by reason, among other reasons, of: Insufficiency of label space for the prominent placing of such word, statement, or information, resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label."

98D-1266

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4. The draft does not address the impact of this inclusion on regulated advertising.

5. The draft does not address how this applies to products where Suitability Petitions have been filed.

6. The draft does not address how the FDA intends to treat labeling which is determined to be out of compliance due to inappropriate claims.

7. The draft does not address if the FDA will require prior approval of labeling for addition of therapeutic equivalence codes.

8. The draft does not address if an incorrect bioequivalency rating is placed on the label or if the rating changes, if the FDA will automatically consider the product misbranded and therefore, subject to regulatory action.

9. The draft does not address the impact on grandfathered drugs.

Sincerely,

LUITPOLD PHARMACEUTICALS, INC.

Barbara Loveland

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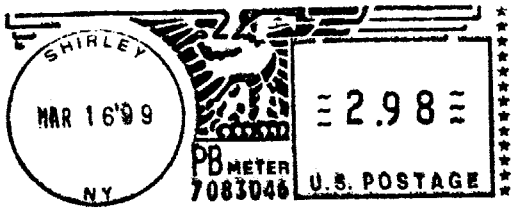
MAIL



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